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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,341	10/13/2000	Hisakazu Kurita	K0448/7003	5123

7590 02/01/2006

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EXAMINER

GHALI, ISIS A D

ART UNIT PAPER NUMBER

1615

DATE MAILED: 02/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,341

Applicant(s)

KURITA ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10/31/05. 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicants' amendment, request for RCE and IDS, all filed 10/31/2005.

Claims 2 and 7-12 have been canceled. Claims 13-19 have been added.

Claims 1, 3-6, and 13-19 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2005 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 3-6, and 13-19 are rejected under 35 U.S.C. 102(a) as being anticipated by JP 10045570 ('570).

JP '570 discloses percutaneous adhesive preparation that has low skin irritation and excellent skin permeability (abstract). The preparation forms an adhesive layer comprising 0.05-20 wt.% of active agent and 0.01-15 wt.% of sodium acetate (abstract; claims 1, 2; page 2, paragraphs 0006, 0008). The adhesive layer is prepared by solvent method, or hot melt method followed by spreading and drying of the adhesive preparation on a base layer, i.e. backing (page 4, paragraphs 0014, 0015). The reference anticipates the claims because it discloses the same method of making the adhesive preparation using the same ingredients, resulting in a composition comprising the ion pairs of the drug with the organic acid salt in melted form or in ionically dissolved form in a solvent, with no powder or particle in the composition after either way of making. If the composition is produced by the dissolving method, the particles size is not important because the particle of any size will dissolve and form ion-pairs with the drug forming new complex particles. If the composition is produced by the hot-melting method, the particles size is not important because the particle of any size will melt and

form ion-pairs with the drug forming new complex amorphous lump. Therefore, the reference anticipates the claims because the claims are directed to adhesive preparation comprising ion-pairs of basic drug with organic acid salt.

4. Claims 1, 3-6 and 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 08-157365 ('365).

JP '365 discloses a transdermal adhesive preparation having remarkable high skin permeation rate and remarkable reduced skin irritation and provides good medicine stability. The preparation forms an adhesive layer in a plaster comprising 0.1-10 wt.% base drug salt and 0.5-5 wt.% of sodium acetate (abstract; page 1 of the translation, claim 6; page 3, paragraph 009). The adhesive layer is prepared by solvent method, or hot melt method followed by spreading and drying of the adhesive preparation on a base layer, i.e. backing (page 4, paragraphs 0015, 0016). The reference anticipates the claims because it discloses the same method of making the adhesive preparation using the same ingredients, resulting in a composition comprising the ion pairs of the drug with the organic acid salt in melted form or in ionically dissolved form in a solvent, with no powder or particle in the composition after either way of making. If the composition is produced by the dissolving method, the particles size is not important because the particle of any size will dissolve and form ion-pairs with the drug forming new complex particles. If the composition is produced by the hot-melting method, the particles size is not important because the particle of any size will melt and form ion-pairs with the drug forming new complex amorphous lump. Therefore, the reference anticipates the claims

because the claims are directed to adhesive preparation comprising ion-pairs of basic drug with organic acid salt.

5. Claims 1, 3-6, 13-19 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,866,157 ('157).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '157 discloses an adhesive composition for matrix patch formulation that improves the permeability of the drug and significantly reduces the skin irritation (col.2, lines 33-36). The adhesive composition forms a layer comprising from 0.1 to 20 % (w/w) of a basic drug and from 0.01 to 15 % (w/w) of organic acid or its salt such as sodium acetate (abstract; col.2, lines 40-60; col.3, lines 9-25, 55-58; examples). The adhesive layer is prepared by solvent method, or hot melt method followed by spreading and drying of the adhesive preparation on paper or backing (col.6, lines 3-16). The reference anticipates the claims because it discloses the same method of making the adhesive preparation using the same ingredients, resulting in a composition comprising the ion pairs of the drug with the organic acid salt in melted form or in ionically dissolved form in a solvent, with no powder or particle in the composition after either way of making. If the

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composition is produced by the dissolving method, the particles size is not important because the particle of any size will dissolve and form ion-pairs with the drug forming new complex particles. If the composition is produced by the hot-melting method, the particles size is not important because the particle of any size will melt and form ion-pairs with the drug forming new complex amorphous lump. Therefore, the reference anticipates the claims because the claims are directed to adhesive preparation comprising ion-pairs of basic drug with organic acid salt.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 3-6, and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10045570 ('570).

JP '570 teaches percutaneous adhesive preparation that has low skin irritation and excellent skin permeability (abstract). The preparation forms an adhesive layer comprising 0.05-20 wt.% of active agent and 0.01-15 wt.% of sodium acetate (abstract; claims 1, 2; page 2, paragraphs 0006, 0008). The adhesive layer is prepared by solvent method, or hot melt method followed by spreading and drying of the adhesive preparation on a base layer, i.e. backing (page 4, paragraphs 0014, 0015). The reference discloses the same method of making the adhesive preparation using the same ingredients, resulting in a composition comprising the ion pairs of the drug with the organic acid salt in melted form or in ionically dissolved form in a solvent, with no powder or particle in the composition after either way of making. If the composition is produced by the dissolving method, the particles size is not important because the particle of any size will dissolve and form ion-pairs with the drug forming new complex particles. If the composition is produced by the hot-melting method, the particles size is not important because the particle of any size will melt and form ion-pairs with the drug forming new complex amorphous lump.

The reference does not teach the mean diameter of the organic acid. The diameter of the organic acid does not impart patentability to the claims in absence of superior and unexpected results. The claims are directed to product by process, and the product is a drug forming ion-pairs with an organic acid salt. The process of production

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of the product included dissolving in a solvent method or heat melting method, and in either method the diameter of the particles of the organic acid salt is not important because the organic acid salt will either dissolve to form a solution or melt to form amorphous lump and then form the ion pair with the drug.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an adhesive produced by dissolving in a solvent method or heat melting method of the drug and the salts of organic acid as disclosed by the reference, and select organic acid with small diameter motivated by the logic that smaller particles will dissolve or melt faster, with reasonable expectation of having an adhesive layer produced by dissolving or melting drug and salt of organic acid that less time consuming. In any event, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

9. Claims 1, 3-6, and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08-157365 ('365).

JP '365 teaches a transdermal adhesive preparation having remarkable high skin permeation rate and remarkable reduced skin irritation and provides good medicine stability. The preparation forms an adhesive layer in a plaster comprising 0.1-10 wt.% base drug salt and 0.5-5 wt.% of sodium acetate (abstract; page 1 of the translation, claim 6; page 3, paragraph 009). The adhesive layer is prepared by solvent method, or hot melt method followed by spreading and drying of the adhesive preparation on a

base layer, i.e. backing (page 4, paragraphs 0015, 0016). The reference discloses the same method of making the adhesive preparation using the same ingredients, resulting in a composition comprising the ion pairs of the drug with the organic acid salt in melted form or in ionically dissolved form in a solvent, with no powder or particle in the composition after either way of making. If the composition is produced by the dissolving method, the particles size is not important because the particle of any size will dissolve and form ion-pairs with the drug forming new complex particles. If the composition is produced by the hot-melting method, the particles size is not important because the particle of any size will melt and form ion-pairs with the drug forming new complex amorphous lump.

The reference does not teach the mean diameter of the organic acid. The diameter of the organic acid does not impart patentability to the claims in absence of superior and unexpected results. The claims are directed to product by process, and the product is a drug forming ion-pairs with an organic acid salt. The process of production of the product included dissolving in a solvent method or heat melting method, and in either method the diameter of the particles of the organic acid salt is not important because the organic acid salt will either dissolve to form a solution or melt to form amorphous lump and then form the ion pair with the drug.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an adhesive produced by dissolving in a solvent method or heat melting method of the drug and the salts of organic acid as disclosed by the reference, and select organic acid with small diameter motivated by the

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logic that smaller particles will dissolve or melt faster, with reasonable expectation of having an adhesive layer produced by dissolving or melting drug and salt of organic acid that less time consuming. In any event, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

10. Claimss1, 3-6, and 13-19 are rejected under 35 U.S.C. 103(a) as being obvious over US 5,866,157 ('157).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

US '157 teaches an adhesive composition for matrix patch formulation that improves the permeability of the drug and significantly reduces the skin irritation (col.2, lines 33-36). The adhesive composition forms a layer comprising from 0.1 to 20 % (w/w) of a basic drug and from 0.01 to 15 % (w/w) of organic acid or its salt such as sodium acetate (abstract; col.2, lines 40-60; col.3, lines 9-25, 55-58; examples). The adhesive layer is prepared by solvent method, or hot melt method followed by spreading and drying of the adhesive preparation on paper or backing (col.6, lines 3-16). The reference discloses the same method of making the adhesive preparation using the same ingredients, resulting in a composition comprising the ion pairs of the drug with the organic acid salt in melted form or in ionically dissolved form in a solvent, with no powder or particle in the composition after either way of making. If the composition is produced by the dissolving method, the particles size is not important because the particle of any size will dissolve and form ion-pairs with the drug forming new complex particles. If the composition is produced by the hot-melting method, the particles size is not important because the particle of any size will melt and form ion-pairs with the drug forming new complex amorphous lump.

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because the organic acid salt will either dissolve to form a solution or melt to form amorphous lump and then form the ion pair with the drug.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an adhesive produced by dissolving in a solvent method or heat melting method of the drug and the salts of organic acid as disclosed by the reference, and select organic acid with small diameter motivated by the logic that smaller particles will dissolve or melt faster, with reasonable expectation of having an adhesive layer produced by dissolving or melting drug and salt of organic acid that less time consuming. In any event, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

Applicants' arguments

11. Applicant's arguments with respect to claims 1, 3-6, 13-19 have been considered but are moot in view of the new ground(s) of rejection.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 5,629,019 disclosed that micronization of compounds accelerates their skin permeation.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595.

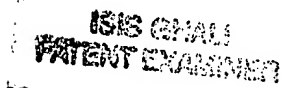
The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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ISIS GHALI
PATENT EXAMINER